Children’s Hospital & Health Center Research Approval

Updated 05/27/04

Introduction

Human subjects research cannot be conducted at Children’s Hospital & Health Center (CHHC) without CHHC approval in the form of a Ready-to-Accrue letter. This includes, but is not limited to, research that involves Children’s patients, space, staff, resources, data or any other source of research materials. The Ready-to-Accrue letter is issued after all the following approvals have been obtained: (1) Financial review and utilization resource approval from Hospital Administration through the Research Review Council; (2) Institutional Review Board (IRB) approval or waiver; (3) logistics approval; (4) budget and contract approval; and (5) for drug studies, approval from the CHHC Pharmacy. Approval from the Institutional Review Board, whether it be Children’s or UCSD’s, does not constitute CHHC approval to begin the research.

The research approval process, summarized in Figure 1, depends on whether or not any investigator on the project is a salaried UCSD faculty member or is a UCSD trainee (student, resident, fellow). If no investigators are UCSD-salaried or UCSD trainees, then the research approval process begins with financial review prior to Children’s Hospital Institutional Review Board submission. If the PI is a salaried UCSD faculty member or is a UCSD trainee, financial review and UCSD IRB submission may occur concurrently.

Who can be a Principal Investigator at Children’s:

Principal Investigators must meet one of the following eligibility criteria:

1. Physician members of the CHHC Medical Staff
2. CHHC job title of Research Scientist--Physician
3. CHHC job title of Research Scientist--Non-Physician
4. Research Scientist in the Laboratory for Research on the Neuroscience of Autism
5. Research Scientist in the Child & Adolescent Services Research Center
6. CHHC employee
7. Faculty member of the UCSD Department of Pediatrics
8. UCSD fellow, resident, or medical student with a mentor who is a member of the CHHC Medical Staff

Co-investigators may include individuals who do not meet the above criteria.
Figure 1. An IRB approval letter does NOT give approval for research to begin at CHHC. Only the Ready-to-Accrue letter gives the investigator approval to begin the research.
How to obtain approval to do research involving Children’s Hospital & Health Center

If no investigator is a UCSD salaried faculty member or a UCSD trainee (student, resident, or fellow):

1. **Complete the** Children's Hospital Financial Review forms: (1) CHHC_budget_resources.xls and (2) CHHC_project_summary.doc. Send the completed forms to Research Administration (Mail Code 5074), Children's Hospital, 3020 Children's Way, San Diego, CA 92123. The title on the forms must match the title to be used on the Children's IRB application. A 5-digit Children's Hospital internal reference number will be assigned to your project. **Use this number** when communicating with Research Administration or the Center for Pediatric Clinical Research.

2. Once submitted, projects will undergo Children's Hospital financial review by Hospital Administration of the budget, resource utilization needs, and scope of the research as it relates to the mission of Children's Hospital.

3. Research Administration will notify the investigator or administrative contact by e-mail when financial review approval has occurred.

4. Following notification that financial review approval has been given, **submit** 5 hard copies of your Children's IRB application to Research Administration at Children's Mail Code 5074.

5. These documents will then be distributed to the individuals at Children's responsible for reviewing the following: (1) protocol review as it relates to the research at Children's (this is different from scientific review, which is a function of the IRB), (2) logistics review, (3) budget, contract, and grant review (depends on the individual project), and (4) pharmacy review for drug studies. Write the Children's internal reference number in the top right corner of the face page of the application.

6. When all Children's administrative approvals have been given and when the Children's IRB has notified Research Administration that an IRB approval letter has been issued, Research Administration will issue the investigator or administrative contact a Ready-to-Accrue letter, which will allow the investigator to begin the research. The IRB approval letter **DOES NOT** give the investigator permission to begin the research.

If any investigator on the project is either a UCSD salaried faculty member or a UCSD trainee (med student, resident, or fellow):

1. **Submit** an IRB application to the UCSD IRB. [http://irb.ucsd.edu/](http://irb.ucsd.edu/)

2. Concurrently with submission of the IRB application to the UCSD IRB, **complete the** Children's Hospital Financial Review forms: (1) CHHC_budget_resources.xls and (2) CHHC_project_summary.doc. Send the completed forms to Research Administration (Mail Code 5074), Children's Hospital, 3020 Children's Way, San Diego, CA 92123. The title on the forms must match the title submitted to the UCSD IRB. A 5-digit Children's Hospital internal reference number will be assigned to your project. **Use this number** when communicating with Research Administration or the Center for Pediatric Clinical Research.

3. Once submitted, projects will undergo Children's Hospital financial review of the budget, resource utilization needs, and scope of the research as it relates to the mission of Children's Hospital.

4. The investigator or administrative contact will be notified when financial review has occurred. Once approval is given, your IRB application will be downloaded from the dual-tracking IRB system. Copies will be distributed to the individuals at Children's responsible for reviewing the following: (1) protocol review as it relates to the research at Children's (this is different from scientific review, which is a function of the IRB), (2) logistics review, (3) budget, contract, and grant review (depends on the individual project), and (4) pharmacy review for drug studies.
5. When all Children's administrative approvals have been given and when the Children's IRB has notified Research Administration that an IRB approval letter has been issued, Research Administration will issue the investigator or administrative contact a Ready-to-Accrue letter, which will allow the investigator to begin the research. The IRB approval letter DOES NOT give the investigator permission to begin the research.

➢ If your study involves transfer of tissue samples or data from Children's to another institution or entity:

If you need a Material Transfer Agreement for your study, contact Lauren Gordon in the Center for Pediatric Clinical Research at lgordon@chsd.org for details.

➢ If your study involves investigators or research associates who will be on Children's Hospital property or who will interact with research subjects face-to-face and who are not currently CHHC staff or CHHC volunteers:

The Children's policy on badging requirements for non-CHHC investigators and research associates is under development.

➢ Research study subjects need to be registered:

For all research protocols,* if a research consent and/or assent form is signed, the research subject must be registered in the hospital's registration system under a “special project number” (SP#).

Copies of research subject consent and/or assent forms, once signed, must be sent for entry into the individual's medical record. The research consent/assent forms will become a part of the record in Chartmaxx (CHHC's electronic medical record system). Originals of the consent/assent forms may be kept in the in specialty clinic record or in the research source documents (if the research study is independent of standard of care visits).

* Research protocols that obtain a total HIPAA waiver from the IRB and do not involve obtaining subject consent are exempt

To determine if registration of research subjects is required in the Children's Hospital Meditech system, the following guidelines are provided:
<table>
<thead>
<tr>
<th>Situation</th>
<th>Meditech registration required?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject is a patient</td>
<td></td>
</tr>
<tr>
<td>Any study for which a parent has to sign a human subjects consent form</td>
<td>Yes</td>
</tr>
<tr>
<td>Patient comes to CHHC for on-site research survey*, research interview, or non-invasive clinical assessment** performed for research purposes tied to a standard of care patient visit</td>
<td>Yes</td>
</tr>
<tr>
<td>Research survey*, research interview, or non-invasive clinical assessment** performed for research purposes is not tied to a standard visit - patient comes to CHHC for the research study procedure</td>
<td>Yes</td>
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<tr>
<td>CHHC investigator/research staff goes to the patient's home to conduct research-related structured interview or non-invasive clinical assessment** performed for research purposes (not tied to a standard visit)</td>
<td>Yes</td>
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<tr>
<td>CHHC investigator/research staff goes to the patient's home for research survey* not tied to a standard visit</td>
<td>No</td>
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<tr>
<td>Treatment studies (e.g., study drug vs. placebo) in departments &quot;owned&quot; by the physician, e.g., Dermatology, Otolaryngology</td>
<td>Yes</td>
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<tr>
<td>Patient comes to CHHC for non-therapeutic, non-lab clinical evaluation done for the purposes of collecting research data</td>
<td>Yes</td>
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<tr>
<td>Non-treatment research studies (e.g., standard of care procedures performed from which research data is collected) in departments &quot;owned&quot; by the physician, e.g., Dermatology, Otolaryngology</td>
<td>Yes</td>
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<tr>
<td>Subject is not a patient (healthy control volunteer)</td>
<td></td>
</tr>
<tr>
<td>Any study for which a parent has to sign a human subjects consent form</td>
<td>Yes</td>
</tr>
<tr>
<td>Subject comes to CHHC for on-site research survey*, research interview, or non-invasive clinical assessment** performed for research purposes</td>
<td>Yes</td>
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<td>CHHC investigator/research staff goes to the subject's home to conduct research-related structured interview or non-invasive clinical assessment** performed for research purposes</td>
<td>Yes</td>
</tr>
<tr>
<td>CHHC investigator/research staff goes to the subject's home for research survey*</td>
<td>No</td>
</tr>
<tr>
<td>Subject comes to CHHC for non-therapeutic, non-lab clinical evaluation done for the purposes of collecting research data</td>
<td>Yes</td>
</tr>
<tr>
<td>Subject comes to CHHC for non-therapeutic, diagnostic procedure or lab evaluation for the purposes of collecting research data</td>
<td>Yes</td>
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</tbody>
</table>

* = No clinically relevant information is being collected with a survey  
** = Non-invasive clinical assessment - e.g., language skill, motor skill, neuro-cognitive, psycho-educational evaluation

Exceptions to the above guidelines will be handled on a case-by-case basis. For additional information, contact Beata Kawamoto, Team Leader, in the Center for Pediatric Clinical Research, at bkawamoto@chsd.org.

For questions, please call Children's Hospital Research Administration at 858-966-5934.